P M A M e m o r a n d u m

Date: October 24, 2002

From: Robert J. De Luca, PMA Team Leader

FDA / Office of Device Evaluation
Division of General, Restorative and Neurological Devices
Restorative Devices Branch

Subject: **TEAM LEADER OVERVIEW**

PMA Number: **P020033** (ORIGINAL PMA)

Device Name: **INDEPENDENCE™ IBOT™ 3000 Mobility System**

Applicant: Independence Technology, L.L.C.

To: Advisory Committee Members

INTRODUCTION

This original premarket approval application (PMA) is submitted by Independence Technology, L.L.C., for the INDEPENDENCE™ IBOT™ 3000 Mobility System.

This PMA application was granted "expedited review" status by FDA on September 13, 2002. Expedited review status was granted because FDA believes the device represents a breakthrough technology with a clear, clinically meaningful advantage over existing technologies and because FDA expects that the device could provide a specific public health benefit in patients with mobility impairments.

The purpose of this team leader overview memo is to present a summary of the reviews conducted by the review team for this PMA.

REVIEW TEAM, PMA ORGANIZATION and ASSIGNMENTS

The premarket scientific review team for this PMA consisted of the following individuals:

- Robert DeLuca, M.S. (Lead Reviewer/Team Leader), CDRH/Office of Device Evaluation/DGRND/Restorative Devices Branch

- Marie Schroeder, M.S., P.T. (Clinical Review), CDRH/Office of Device Evaluation/Division of General, Restorative, and Neurological Devices

- Donald Witters (Electromagnetic Compatibility Review), CDRH/ Office of Science and Technology /Division of Physical Sciences/Electrophysics Branch

- Joseph Jorgens (PMA Software Review), CDRH/Office of Science and Technology/Division of Electronics and Computer Science/Medical Electronics Branch

- Phyllis Silverman, M.S. (Statistical Review), CDRH/Office of Surveillance and Biometrics/Division of Biostatistics

- Laurel Mendelson (Human Factors and Patient Labeling Review), CDRH/Office of Health and Industry Programs/Division of Device User Programs and Systems Analysis

- William Defibaugh (Manufacturing/GMP Review), CDRH/Office of Compliance/Division of Enforcement III

- Levering Keeley (Bioresearch Monitoring Review), CDRH/Office of Compliance/Division of Bioresearch Monitoring

The following table summarizes the major sections of the PMA and the organization of these sections.

Volume	Pages	Section Name
01	All	Background and Summary Information
02	All	Device Description
03 thru 09	All	Software Documentation
10	All	Qualification Testing Reports
11, part 1	001-173; 232-341	Qualification Testing Reports
11, part 2	174-231	Electromagnetic Compatibility Testing Report
12	All	Qualification Testing Reports
13	All	Qualification Testing Reports
14	All	Clinical Testing
15	All	Clinical Testing
16	All	Clinical Testing
17	All	Miscellaneous
18-19	All	Labeling
20	All	Labels
Module M990021/M2	All	Manufacturing

SUMMARY of REVIEWS

1. ***ENGINEERING REVIEWS*** *(PMA Volumes 2-13)*

- **Device Description and Non-Clinical Sections** (PMA Volume 2 and Volumes 10 through 13)

  The device description and non-clinical review of this PMA was performed by Robert J. DeLuca. A copy of this review may be found in a separate memo in Tab 4 of your binder.

- **Electromagnetic Compatibility Section** (PMA Volume 11, pages 174-231)

  The EMC review of this PMA was performed by Donald Witters. A summary of the major findings from Mr. Witters' review may be found in Tab 6 of your binder.

- **Software Section** (PMA Volumes 3 through 9)

  The software review of this PMA was performed by Joseph Jorgens. A copy of this review may be found in a separate memo in Tab 6 of your binder.

2. ***CLINICAL REVIEW*** *(PMA Volumes 14-16)*

   The clinical review of this PMA was conducted by Marie A. Schroeder. A copy of this review may be found in a separate memo in Tab 5 of your binder.

3. ***STATISTICAL REVIEW*** *(PMA Volumes 14-16)*

   The statistical review of this PMA was performed by Phyllis Silverman. A summary of the major findings from Ms. Silverman's review may be found in Tab 6 of your binder.

4. ***HUMAN FACTORS and PATIENT LABELING REVIEW*** *(PMA Volume 2 and Volume 18, pages 001 through 251)*

   The human factors and patient labeling review of this PMA was performed by Laurel Mendelson. A copy of this review may be found in a separate memo in Tab 6 of your binder.